

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

(a) *Identification.* A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4710 Esophagoscope (flexible or rigid) and accessories.

(a) *Identification.* An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the esophagoscope and is intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4720 Mediastinoscope and accessories.

(a) *Identification.* A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which

attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracically and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4750 Laryngostroboscope.

(a) *Identification.* A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation. The device operates by focusing a stroboscopic light through a lens for direct or mirror reflected viewing of glottic action. The light and microphone that amplifies acoustic signals from the glottic area may or may not contact the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.

(a) *Identification.* A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasosinuscope, nasoscope, postrhinoscope, rhinoscope, salpingoscope, flexible foreign body